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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,958	06/20/2000	Jihyun Francis Kim	19603/3286(CRF D-2062B)	5427

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/596,958	KIM ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 0200*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10 and 40-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-3 and 5-10* is/are allowed.

6)☒ Claim(s) *40-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3, 5-10 and 40-48 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objection to claims 2-3 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, is withdrawn in light of applicant's amendment to claim 1 that makes it allowable.

4. The objection to claims 2-5, 7 and 9-10 because they start with an improper article is withdrawn in light of Applicant's amendment to the claims.

5. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment to the claim.

6. The rejection of claims 6-7 and 10 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements is withdrawn in light of Applicant's amendment to the claims.

Claim Rejections - 35 USC § 112

7. Claims 40-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO:1 or encoding SEQ ID NO:2, does not reasonably provide enablement for nucleic acids that hybridize under conditions of unspecified stringency to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as

set forth in the Office action mailed 14 October 2003, as applied to claims 1 and 4-10.

Applicant's arguments filed 15 April 2004 have been fully considered but they are not persuasive.

Applicant urges that claim 40 recites the hybridization conditions and the function of the encoded protein (response pg 4).

This is not found persuasive because the specification does not teach the sequence of the claimed nucleic acids.

Applicant urges that only objective enablement is required; the specification must only teach one of skill in the art how to obtain the claimed nucleic acid. Applicant urge that they have identified a single species of hrpW by nucleotide sequence and that one of skill in the art could use it and the recites hybridization conditions to find others; cloning and assaying the nucleic acid would only require routine techniques. Applicant urges the office's position is unsupported by law (response pg 4-5).

This is not found persuasive because the specification must teach how to make the claimed nucleic acid, not how to find it.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1016:

> Conception of generalized approach for screening DNA library that might be used to identify and clone erythropoietin gene of then-unknown constitution is not conception of "purified and isolated DNA sequence" encoding human EPA, since it is not "definite and permanent idea of the complete and operative invention."

Applicant urges that as evidence that one of skill in the art would have expected that hybridizing nucleic acid encode hypersensitive response elicitor, they include an alignment of GenBank Accession AY237642 with SEQ ID NO:1 to show the sequences are highly identical; thus, the sequences would hybridize to one another (response pg 5).

This is not found persuasive because the specification does not teach the sequence.

See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

8. Claims 40-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 14 October 2003, as applied to claims 1 and 4-10. Applicant's arguments filed 15 April 2004 have been fully considered but they are not persuasive.

Applicant urges that one of skill in the art would recognize that applicant was is possession of isolated hrpW-encoding nucleic acids from other *Erwinia* species because of their identification of the sequence of one species and demonstration that it hybridized to DNAs from other species (response pg 6).

This is not found persuasive. There are at least 14 *Erwinia* species, including *E. amylovora, E. aphidicola, E. billingiae, E. carotovora, E. chrysanthemi, E. chrysantum, E. mallotivora, E. papayae, E. persicina, E. psidii, E. pyrifoliae, E. rhapontici, E. salicis,* and *E. tracheiphila.* The instant specification only describes only one nucleic acid encoding a hypersensitive response elicitor within the scope of the claims.

Applicant urges that SEQ ID NO:2 shares properties with other hypersensitive response elicitors, but also has two domains not present in HrpN, HrpZ and PopA, and that the HrpW of a *Pseudomonas* species did not hybridize to the genomic DNA of several *Erwinia* pathogens, as taught in Charkowski et al (response pg 6).

This is not found persuasive because Applicant has not described the structural elements common to the claimed nucleic acids encoding other HrpW hypersensitive response elicitors but not to nucleic acids encoding other HrpW hypersensitive response elicitors.

Applicant urges that given the above, one of ordinary skill in the art would have understood that applicant was in possession of SEQ ID NO:1 and nucleic acids that hybridize to SEQ ID NO:1 from other *Erwinia* species (response pg 7).

This is not found persuasive because Applicant did not describe the sequence of those other nucleic acids nor did they deposit plasmids comprising those nucleic acids. Applicant is claiming nucleic acids isolated from *E. carotovora, E. chrysanthemi,* and *E. salicis*, but the sequence of those nucleic acids is not described. The claims are drawn to isolated DNAs; Southern hybridization is not the same thing as isolation of DNAs.

Applicant urges that the Written Description Guidelines do not state that one disclosed sequence cannot provide support for a genus. Applicant also urges that *Eli Lilly* does not apply because they merely described a general procedure for obtaining human insulin cDNA, while in the instant case Applicant claims SEQ ID NO:1 and Erwinia DNAs that hybridize to SEQ ID NO:1; thus, the instant claims are most like the subject matter in *Lilly* that was deemed adequately described (response pg 7-8).

This is not found persuasive because a description of the HrpW sequence from *E. amylovora* does not provide support for the hrpW sequence from *E. carotovora, E. chrysanthemi, E. salicis* or other *Erwinia* species. Eli Lilly applies because in that case human insulin DNA was claimed, but not described. In the instant case, the hrpW sequence from *E. carotovora, E. chrysanthemi, E. salicis* or other *Erwinia* species is claimed, but not described. A partial description of hybridization conditions does not overcome this lack.

9. Claims 1-3 and 5-10 are allowed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
June 17, 2004

ANNE KUBELIK
PATENT EXAMINER